REMARKS

Claims 1, 7-10, and 16-19 are in this application and are presented for consideration. By this Amendment, Applicant has amended claims 1, 7, 10 and 19. Claims 3 and 4 have been canceled, with subject matter of these claims added to claim 1. Claims 12 and 13 have been canceled, with subject matter of these claims added to claim 10. Similar changes have been made to claim 19.

Claims 1 and 10 and 19 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Burke in view of Papadofrangakis et al. (US 4,217,909).

The present invention is based on the inventor's finding of a new component which varies at a frequency of tens to hundreds of Hz superimposed over the heart cyclic variations (CV). The component is different from and in addition to the intensity of ultrasonic integrated backscatter (IB) from the heart wall that is known to manifest cyclic variations (CV) matching the pulsation of the heart, namely a falling in the systole and rising in the diastole. The signal of interest is observed using a frequency of a few kHz.

The present invention makes it possible to measure the ultrasonic backscatter from the heart wall at a frequency of a few kHz in order to obtain a variation frequency (or variable cycle). As discussed in the specification, this is very significant with regard to providing information about the heart tissue itself with the information being provided for the first time without invasive surgery.

The prior art as a whole (each of Burke and Papadofrangak) lacks any teaching or suggestion of observing or detecting the component relating to the above finding. As such,

Burke and Papadofrangakis cannot and do not present any teachings or suggestions with regard to steps of the method or the device for investigating this using a frequency of a few kHz, and to measure the component which varies at a frequency of tens to hundreds of Hz in the ultrasonic backscatter in the heart wall.

In the reply to arguments there is the statement that attacking references individually cannot itself show nonobviousness. However, the prior art must be considered for what it fairly teaches. The individual teachings are significant with regard to obviousness and whether there is information which renders the claimed subject matter obvious. One basic acceptable consideration is that prior art references deal with different situations, purposes, functions etc. Papadofrangakis deals with using ultrasound for comparison of signals to detect blood flow direction. This is not for imaging. Burke presents an ultrasound system for measuring differential backscatter across a selected volume of tissue or organ for imaging. Although both references mention ultrasound, the devices are very different with different functions and purposes. It is certainly reasonable to focus on the purpose and teachings of the references to determine whether the references present information which render the subject matter obvious. This is a basic consideration of the facts which are involved with a determination of obviousness, namely A) Determining the scope and content of the prior art; (B) Ascertaining the differences between the claimed invention and the prior art; (C) Resolving the level of ordinary skill in the art. The scope and nature of the prior art are noted in an Applicant's analysis and the teachings are important in determining obviousness. Such an analysis is not an attack on an individual reference but a review the facts.

Applicant's newly presented claims include features from dependent claims 3 and 4 relating to features which are important with regard to the overall method and system in which are not obvious in view of the prior is all. The claims also highlight that is not the variable cycle of the heart that is being measured but instead a signal superimposed on the heart's cyclic variations. This concept was already present in the claims but is further highlighted so the claim is not misinterpreted. It is believed that the claims as now presented clearly patentably define over the prior art as a whole. As the issues have already been presented in the overall application, it is requested that the claims be favorably considered and that the application be allowed based on this submission.

Burke (U.S. Patent 4,803,994) disclose a system for measuring a backscatter intensity (column 2, lines 61-68) across a selected volume of tissue or organ (column 1, lines 52-53) by using two frequencies of 2.5 MHz and 3.6 MHz (column 4, lines 63-64). Burke is clearly interested in a frequency range which is not the purposes of Applicant's invention. The prior art does not provided teachings or suggestions which would result in a significant change to this frequency range. Burke needs this frequency range for the particular tissue architecture that is to be represented. There is no teaching in the prior art as a whole to send signals at different frequencies and to measure different backscatter signals. Burke does not provide teachings or suggestions with regard to measuring the backscatter intensity from a heart wall by using a frequency of a few kHz. Nothing in the prior art provides a teaching to do this. As Burke is focused on using a few MHz frequency, the reference provides no suggestions for the person of ordinary skill in the art to provide a drastic change in the frequency of interest.

Further, with the Burke apparatus it is impossible to measure the component which varies at a frequency of tens to hundreds of Hz in the ultrasonic backscatter in the heart wall. Burke fails to teach or suggest (1) calculating a displacement waveform of the region of interest (ROI) by applying a phased tracking method, (2) changing a position and size of the region of interest (ROI) based on the calculated displacement waveform, and (3) calculating the plurality of backscattering intensity signals in one pulsation of the heart.

Claims 1, 10 and 19 now also highlight the important feature of claims 3 and 4 and highlight the inventive aspect of the invention in which a backscatter intensity at a region of interest (ROI) in a "heart wall" is measured by using a frequency of "a few kHz". The present invention (1) calculates a displacement waveform of the region of interest (ROI) by applying a phased tracking method, (2) changes a position and size of the region of interest (ROI) based on the calculated displacement waveform, and (3) calculates the plurality of backscattering intensity signals in one pulsation of the heart. Further, the prior art fails to suggest the crux of the invention wherein the variation frequency is used based on its correlation to muscle fitness so as to provide detailed information on local tissue characteristics of the cardiac muscle. The variation frequency of the backscattering intensity is a frequency of tens to hundreds of Hz, a frequency that is not at all of interest in Burke.

Burke (U.S. Patent 4,803,994) discloses measuring a backscatter intensity (column 2, lines 61-68) across a selected volume of tissue or organ (column 1, lines 52-53) by using two frequencies of 2.5 MHz and 3.6 MHz (column 4, lines 63-64). With only the Burke reference, the claimed combination of features is clearly not obvious. However, the secondary reference

Papadofrangakis (U.S. Patent 4,217,909) does not provide any suggestions which are useful is support of the position that the invention is obvious. The teachings of Papadofrangakis in combination with the teachings of Burke do not lead to the combination as claimed.

Papadofrangakis disclose measuring a Doppler frequency shift (abstract) in blood flow (abstract) by using the audio spectrum of about 0.2-8 KHz (column 6, lines 50-51). Papadofrangakis explains the frequency range and aspects of the measurement at column 4, lines 8 – 22:

> *"...The instrument being described has pulse repetition frequency (PRF) settings of 4 KHz, 8 KHz, and 16 KHz. For high values of velocity flow in sample volumes at close ranges, detection is accomplished by using a 16 KHz PRF. The velocity resolution is relatively poor. Superior velocity resolution at low flow velocities and long ranges is achieved by the 4 KHz PRF. To provide additional flexibility in the choice variable to the user, there is an intermediate setting of 8 KHz PRF. The chosen PRF (ultrasound pulse repetition frequency) values in the Doppler mode are considerably higher than those provided in imaging, and the transmitter subsystem is capable of providing appropriate excitation intervals for both modes of operation.*

This at least shows that Papadofrangakis is presenting teachings relating to a particular problem of detecting a Doppler shift, with this being very different from imaging. Papadofrangakis then goes on to direct the person skilled in the art to a particular frequency range for making a measurement based on aspects of blood flow (column 4, lines 37 – 58),

namely:

> *The instrument measures only the component of mean velocity 38 in the direction of the transmitted ultrasound beam defined by scan line 36. The formula relating Doppler frequency shift and velocity is where DELTA.f=frequency shift, f.sub.o =ultrasound emission frequency, v=mean velocity of blood flow, and c=speed of sound in tissue (1450 m/sec). The ultrasound emission frequency for cardiac scanning is in the order of 2-5 MHz. The range of human blood velocities is known and Doppler shifts are in the audio spectrum of about 0.2-8 KHz. The red blood cell population of sample volume 35 is constantly changing and it is necessary to get a number of samples of frequency shifted echoes in order to calculate an accurate value of velocity. Red blood cells moving past the sample volume backscatter ultrasonic energy containing a spectrum of Doppler frequencies, and these correspond to the distribution of velocities present in the sampled region.*

The choice of frequency is not for imaging. The choice of frequency is based on blood flow velocity. Accordingly, there is no suggestion to change the imaging scheme of the primary reference based on blood flow velocity frequency noted in the secondary reference. Further, Papadofrangakis does not disclose any measurement of the backscatter intensity at a heart wall. According to Papadofrangakis, Doppler frequency shifts can only be measured in blood flow in the heart. Thus, Papadofrangakis presents no teaching and no suggestion as to measuring a "backscatter intensity" **at a "heart wall"**. The references together do not present teachings

of the features claimed. Further, the references present teachings which are for different purposes and direct the person of ordinary skill in the art in different directions.

Burke does not disclose a measuring of the backscatter intensity from a heart wall by using a frequency of a few kHz. By using a few MHz frequency, it is impossible to measure the component which varies at a frequency of tens to hundreds of Hz in the ultrasonic backscatter in the heart wall. Thus, Burke has no idea to use a frequency of "a few kHz", and to measure a "backscatter intensity" at a "heart wall". Papadofrangakis is interested in a frequency range (the blood flow range) for a comparison, namely for detecting a Doppler shift to detect direction of blood flow. This presents absolutely no suggestion as to modifying Burke or using features of Burke in combination to provide the combination of features claimed.

Further, both of Burke and Papadofrangakis fail to teach and fail to suggest (1) calculating a displacement waveform of the region of interest (ROI) by applying a phased tracking method, (2) changing a position and size of the region of interest (ROI) based on the calculated displacement waveform, and (3) calculating the plurality of backscattering intensity signals in one pulsation of the heart. Accordingly, the combination of Burke and Papadofrangakis does not teach and does not suggest the present invention. On the contrary, only with the present invention is there measured a "backscatter intensity" at a region of interest (ROI) in a "heart wall" by using a frequency of "a few kHz". This is a new development and cannot be considered obvious as the prior art does not present teachings or suggestions which include the claimed features. No obvious combination of known features

will result in the invention as claimed.

Further, the present invention provides features that are not contemplated in the teachings of the prior art. The invention (1) calculates a displacement waveform of the region of interest (ROI) by applying a phased tracking method, (2) changes a position and size of the region of interest (ROI) based on the calculated displacement waveform, and (3) calculates the plurality of backscattering intensity signals in one pulsation of the heart. As this is neither taught nor suggested by the prior art, the combination claimed should be considered nonobvious and patentable.

It is respectfully requested that the rejections be reconsidered in view of the claims as now presented. Further and favorable action on the merits is requested.

Respectfully submitted
for Applicant,

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Attached: Petition for Three Month Extension of Time

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SHOULD ANY OTHER FEE BE REQUIRED, THE PATENT AND TRADEMARK OFFICE IS HEREBY REQUESTED TO CHARGE SUCH FEE TO OUR DEPOSIT ACCOUNT 13-0410.